Substitute Form PTO/SB/08A/B
(Based on PTO 04-07 version)

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	10/699,987-Conf. #5359
Filing Date	November 3, 2003
First Named Inventor	Wing-Kee P. Cho
Art Unit	1615
Examiner Name	H. N. Sheikh
Attorney Docket Number	025444.1059-US02

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number-Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA*	US-5,487,901	01-30-1996	Conte et al.	
	AB*	US-5,508,042	04-16-1996	Oshlack et al.	
	AC*	US-5,997,903	12-07-1999	Dietrich et al.	
	AD*	US-6,114,346	09-05-2000	Harris, et al.	
	AE*	US-6,265,414	07-24-2001	Harris, et al.	
	AF*	US-6,432,972	08-13-2002	Salmun, et al.	
	AG*	US-6,709,676-B2	03-23-2004	Cho	
	AH*	US-6,979,463-A1	12-27-2005	Kou	
	AI*	US-7,211,582	05-01-2007	Aberg et al.	
	AJ*	US-7,214,683	05-08-2007	Aberg et al.	
	AK*	US-7,214,684-A1	05-08-2007	Aberg et al.	
	AL*	US-2002/0123504-A1	09-05-2002	Redmon et al.	
	AM*	US-2004/0097536-A1	05-20-2004	Cho	
	AN*	US-2006/0079489-A1	04-13-2006	Redmon et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3]-Number[4]-Kind Code[5] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	BA	EP-0173928-B1	06-13-1990	AB Leo		√
	BB	EP-0655744-B1	01-05-2000	NEC Corporation		√
	BC	EP-1112738-A2	07-04-2001	Schering Corporation		√
	BD	WO-94/09761-A1	05-11-1994	Kwan et al.		√

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	CA	Connors, et al., Chemical Stability of Pharmaceuticals, a Handbook for Pharmacists, 135-159 (John Wiley & Sons 1986).	
	CB	Technology of Drug Forms, Educational Literature for Students of Pharmaceutical Institutes, Vol. 2, 134, 187, 188, 189 (L.A. Ivanova, ed.) (Moscow, "Meditsina" 1991).	
	CC	Food and Drug Administration / Center for Drug Evaluation and Research, Guidance for Industry -- Q3B Impurities in New Drug Products (November 1997).	

Examiner Signature		Date Considered	

Substitute Form PTO/SB/08A/B
(Based on PTO 04-07 version)

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	2	of	2

Complete if Known	
Application Number	10/699,987-Conf. #5359
Filing Date	November 3, 2003
First Named Inventor	Wing-Kee P. Cho
Art Unit	1615
Examiner Name	H. N. Sheikh
Attorney Docket Number	025444.1059-US02

	CD	Food and Drug Administration / Center for Drug Evaluation and Research, Guidance for Industry -- Dissolution Testing of Immediate Release Solid Oral Dosage Forms (August 1997).	
	CE	Food and Drug Administration / Center for Drug Evaluation and Research, Guidance for Industry -- SUPAC-MR: Modified Release Solid Oral Dosage Forms, Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalance Documentation (September 1997).	
	CF	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, ICH Harmonised Tripartite Guideline -- Impurities in New Drug Prodcuts Q3B(R2), Current Step 4 Version (June 2, 2006).	
	CG	USP 30 / NF 25, Vol. 1, 277-284 (2007).	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	